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Clinical trials are claims support data, need for paradigm change

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In the last few months there has been a lot of focus on potential exaggerated or misleading or unproven claims made on a number of products which include foods and products in food format or products which are touted for various health benefits. The column in the last issue also dealt with need for self-regulation and role of agencies like Advertising Standards Council of India (ASCI). The need for innovators and industry to adhere to and comply with decisions given by ASCI have been underscored by the courts. Since the future of innovations especially in the area of supplements and nutraceuticals that will hit the market will solely depend on, amongst other factors, the genuineness of the claims for such food products which will build confidence in the sector, this month touches upon the issue.

The Nutraceutical Regulations notified by Foods Authority on November 24, 2016 to be complied with from January 1, 2018 has provided for various categories - health supplements, nutraceuticals, food for special dietary use (FSDU), other than infants, and those products intended to be taken under medical advice, food for special medical purposes (FSMP), food with added probiotic ingredients, food with added prebiotic ingredients, speciality foods containing plant or botanical ingredients with safe history of usage and novel foods. In addition, the sector will continue to see some packaged foods under proprietary food category apart from other standard foods many of them also will be sold in pre-packaged condition to meet the increasing demand of working men and women who seek convenience. Marketers will naturally want to make various types of positioning statements and claims on such packaged foods and supplements.

It is to be recognised that Indian Nutra Regulations is perhaps one of those regulations that has provided broad guidelines for such claims. These claims have been listed as those permitted in the Nutra Regulation along with broad guidelines. The intention of use, providing nutrition, the nutrition content and the name of nutrient, comparative nutrient contents, linkages to the alleviation of deficiencies by those nutrients, and similarly the nutritional content / comparative content / linkages to alleviation of deficiencies of nutritionals are permitted claims. The difference between nutrient and nutritional is broadly nutrients are primarily vitamins, minerals

and amino acids for most of which the need role and recommended dietary allowances (RDAs) are available. All other ingredients are referred as nutritionals which also form part of food and are required to provide various functionalities like – fibres, phytocompounds, enzymes, probiotics etc. For this latter group, generally, RDAs are not at all available. In addition to these content claims, the regulations permit various health benefit claims such as – maintaining health, disease risk reduction, prevention and protection. The broad guidelines involve - no drug like claims, should not be misleading, should not be exaggerated, should be factual and based on supporting data.

It is common that regulators and many scientists are not able to make the distinction between factual and data based claims and the way to generate such data. It is only that food scientists and nutritionists are trained to understand supporting data for claims for food and supplements. Most often the term “Should be evidence based” is stated. Evidence base is normally understood to be the same level and design as described for evidence based drugs long ago described and developed by Saket. The readers are encouraged to google up this term resulting in number of slide shares and scholarly articles. In this kind of evidence generation it demands for controlled studies; statistically significant; hypothesis testing; placebo & / or positive control; randomisation; blinding and a host of other requirements.

The design and requirement also suffers from inability to measure or study more than one benefit or outcome. Since such studies normally called as clinical trials, test a pre-decided hypotheses, if the results of the trial does not prove the hypotheses (if the outcome of the variable measured falls short even marginally from the decided percentage response) the tested material will be declared as non-effective. Such an evidence generation, many believe is more applicable to serious drugs and pharmaceuticals and not necessarily for foods and supplements for a variety of scientific reasons. Recognising this aspect, the foods regulations including the Nutra Regulations has paved way for a paradigm shift in claims support data need and methods of generation which is laudable.

The regulations provide provisions for a number of types and nature of claims – support data

- That lead to ingredients (nutrient or nutritional)
- Available scientific literature

- Traditional texts
- Post market data or consumer studies
- Cohort or retroactive studies (eating pattern and health benefits)
- Epidemiological international and national data
- Other forms of well documented data
- Consensual, congruent and concurrent validity studies
- Health promotive and disease risk reduction – literature / human efficacy and safety data of the nutrient
- Not only controlled clinical trials for efficacy and safety data
- Nutra epidemiological data
- Qualified structure function claims for specific organ or function which are comprehensible to consumer
- Prohibits implied claims of curing a disease (prevents bone fragility in post-menopausal women)
- Prohibits implied claims of curing a disease – product name being used such as cancer cure, through pictures, vignettes, symbols (ECG tracing or lipid profiles etc.)
- Distinguishes nutrient / nutritional ingredient led claims vis-à-vis product led claims

Even if one undertakes a clinical trial like study for food and supplements type of products, these guidelines permit not necessarily measuring variables like biomarkers / blood bio chemistry / digitised organ performance recordings like ECG or EEG or spirometry etc. Measurement of what are termed “outcome studies” apply as more relevant for the foods and supplements category. Adequately studied outcomes, though subjective but objectively graded in statistically significant number of subjects form good quality claims support data. Many market research studies involving pre and post intervention studies through interviews, case diaries, consumer diaries undertaken with well written protocols and statistical plans would form

such claims support data. Hence, there is a need to change the mindset from clinical trial to claims support data through intervention studies.

The area needs a lot of further input to support the authority, regulators and the sector. Some of the inputs are listed.

- Develop skills and competencies for scientific writing and data analytics
- Develop skills and competencies to do other forms of claims support data generation
- Solve problems of compliance to intervention protocols as most studies would be of long duration
- Expand focus on preventive and social medicine subjects to develop skills in undertaking – population studies / epidemiological studies / cohorts and retroactive studies
- Collectively contribute by developing more detailed guidelines on conduction of these studies
- Encourage undertaking nutraceutical intervention studies also in academia and not do only drug trials, especially in medical, pharmacy and such institutions
- Collectively develop guidelines for concurrent validity studies – PMS studies through multiple practitioners (physicians / dieticians / health counsellors / TM practitioners)
- Collectively promote development of IT tools for these studies

While doing so the basic essence of any human studies should be involving no compromise on volunteer safety and rights protection, adequate informed consent for participation, adequate protection of identity and confidentiality, adequate compassionate care giving in studies to the participants, helping drafting of claims statements in consumer-friendly language that are based on data / facts. Skills for drafting qualified structure function claims for specific organ or function which are comprehensible to consumers based on intervention studies or other claims support data as described above also need to be developed.

It would be appropriate if the readers send inputs or documents they have seen related to this topic that can help in developing further guidelines on this area. Here is a big opportunity to shape the future of scientific and logical claims support data generation landscape. Is anyone

listening?

Read online: https://nuffoodsspectrum.in/news/2/11237/clinical-trials-are-claims-support-data-need-for-paradigm-change.html
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